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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,513	05/17/2000	KAORU MURATA	0425-0781P	3356

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/554,513		MURATA ET AL.	
	Examiner		Art Unit	
	Samuel P. Siefke		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/26/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status

This Office Action is in response to the arguments presented in the RCE dated 2/23/06 and the Applicant initiated interview on 4/06/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruijten (USPN 4,554,071).

Ruijten discloses a pre-column for preconcentrating substances to be chromatographed along with a separating column. The system comprises column that is filled with a suitable carrier material or adsorption agent. For HPLC examination of body fluids is suitable, pre-treated silica gel, such as silica gel made water-repellent (hydrophobated) is used. For other applications, other carrier materials usual in the liquid chromatographic technique, such as aluminium oxide or ion exchange resins, may also be used. The carrier material is enclosed in the column between two filters, for example, of sintered metal. The Examiner submits that the two sintered metal filters are

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the membranes for diffusing the target component and the silica gel that is placed between the two filters is the membrane for adsorbing the target component. A sample of the liquid to be examined is applied to the column by means of a tube with connected syringe, or, if larger volumes are concerned, by means of a pump. The pre-column is then connected downstream to a separation column or chromatography column, which column is also conditioned in the usual manner. The separation column contains the same material as the pre-column. The adsorbed material is then eluted in the separation column by means of a suitable solvent or solvent mixture, after which the separation column is eluted preferably with the same solvent or solvent mixture (col. 4, lines 3-68; col. 5, lines 1-12; col. 8, lines 36-56). The pre-column has a length of 15 cm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruijten (USPN 4,554,071) in view of Singleton (USPN 5,462,660).

Ruijten discloses a pre-column and a separator as discussed above.

Ruijten does not teach routing of samples to the columns in a specific manner.

Singleton teaches a chemical analysis which comprises a system for separating compounds through a specific flow path. The flow path consisting of a transfer pump, an injector, a switching valve, a pre-column, a switching valve, a solvent mixer, a switching valve, a transfer pump, a switching valve, a separation column and a detector in this order (see fig. 1; col. 3, lines 36-60). It would have been obvious to one having an ordinary skill in the art at the time the invention was made because this flow path is known in the industry of liquid chromatography for use of separating a plurality of compounds.

Regarding the adsorbing membrane having a thickness of 0.2 to 2mm. It would have been obvious to one having an ordinary skill in the art to modify the thickness of the membrane depending on concentrated the user would want the sample to be. See In re Rose, 105, U.S.P.Q. 237.

Response to Arguments

Applicant's arguments filed 2/23/06 have been fully considered but they are not persuasive. The Applicant argues, "The reference fails to teach that the carrier material is in the form of a membrane." During the interview with Jim Hallowick, the Examiner

explained that that the two sintered metal filters are the membranes for diffusing the target component and the silica gel that is placed between the two filters is the membrane for adsorbing the target component. In the specification of the instant application on page 6, "the diffusion membrane may be placed on the both sides of the absorption membrane." This is specifically what Ruijten states on column 4, lines 5-24.

Conclusion

Because there were no claim amendments filed after the Final rejection or with the filing of the RCE (2/26/06), only arguments were presented with the RCE. All the claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



April 6, 2006



**JEFFREY SNAY
PRIMARY EXAMINER**